ADJUNCT CLINICAL STUDY
REVISION COHORT

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ABSTRACT

The McGhan Medical Corporation Silicone-Filled Breast Implant Adjunct Clinical Study is a prospective, 5-year, multi-center clinical study conducted to examine the safety of McGhan Silicone-Filled Breast Implants for reconstruction and revision patients. This report presents the results from the revision cohort through 3 years post-implant.

Data from 9,881 patients who received 19,099 silicone-filled breast implants for the purpose of unilateral or bilateral revision of existing breast implants are presented in this report. The extract date of the database used for this report is August 30, 2002. The revision patients were enrolled between April 27, 1998 and August 21, 2002.

The safety data collected in this study are complications (e.g., device rupture, capsular contracture) and reoperations involving the breast/chest area (e.g., implant replacement/removal). Safety data is collected at scheduled follow-up intervals (1 year, 3 years, and 5 years post-implant) as well as during unscheduled visits. At all scheduled follow-up visits, both the patient's and physician's level of satisfaction with the breast implantation is assessed.

As of this report, 326 (3.3%) of the 9,881 implanted patients have been discontinued from the study due to removal of all study devices (n=126), patient choice (n=112), other reasons (n=74; e.g., patient moved out of the country), or death (n=14). The causes of the patient deaths were cancer, murder, 9/11/01 terrorist attack, suicide, old age, and non-implant related medical conditions (e.g., stroke). Taking into account patients who died or had all study devices removed without replacement with other study devices, follow-up compliance was 43.9% at the 1-year follow-up visit and 19.9% at the 3-year follow-up visit.

To estimate the risk of complications following implantation, Kaplan-Meier survival analysis was conducted on the time to first occurrence of each event. Table 1 of this abstract summarizes the 3-year by-patient risk rate associated with various complications, including the following types of outcomes:

- General Breast Surgery Complications (e.g., breast pain)
- Breast Implant Surgery – Cosmetic Complications (e.g., wrinkling/rippling, implant palpability/visibility)
- Breast Implant Surgery – Non-Cosmetic Complications (e.g., capsular contracture, implant rupture)

The complications with the highest 3-year risk rate by patient were capsular contracture (20.0%), implant palpability (12.1%), and wrinkling (10.6%). All other complications occurred at a by-patient risk rate of less than 10.0%.

A total of 892 patients underwent 982 reoperations through 3 years post-implant, with a 3-year by-patient risk of reoperation of 34.5%. By the end of the 3-year post-implant visit, 576 patients had 791 primary study devices removed, with a 3-year by-patient risk of implant replacement/removal of 24.1%.

More than 90% of physicians indicated being satisfied with the results of breast implant surgery at both the 1-year and 3-year visit intervals. Similarly, most patients indicated being satisfied with the results of their breast implant surgery at both the 1-year (90.1% of patients) and 3-year (88.2% of patients) visit intervals. On a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians and patients ranged between 4.2 and 4.4 during each follow-up interval.

Table 1. Adjunct Clinical Study - Revision Cohort Summary of 3-Year Risk Rate for Specific Complications		
Complication	**3-Year Risk By Patient**	**3-Year Risk By Implant**
Capsular Contracture	20.0%	15.2%
Implant Palpability	12.1%	9.3%
Wrinkling	10.6%	8.3%
Asymmetry	9.8%	N/A
Breast Pain	7.8%	5.6%
Implant Malposition	7.3%	4.8%
Implant Visibility	6.9%	5.2%
Loss of Nipple Sensation	3.7%	3.1%
Capsule Calcification	3.4%	2.4%
Implant Rupture	2.7%	1.8%
Hypertrophic Scarring	2.0%	1.5%
Nipple Hypersensitivity	1.9%	1.5%
Swelling	1.9%	1.4%
Skin Paresthesia	1.4%	0.8%
Nipple Paresthesia	1.1%	1.0%
Redness	1.0%	0.6%
Other Complications	1.0%	0.6%
Bruising	0.7%	0.5%
Infection	0.7%	0.4%
Skin Hypersensitivity	0.7%	0.6%
Delayed Wound Healing	0.6%	0.4%
Implant Extrusion	0.6%	0.6%
Skin Rash	0.6%	0.4%
Hematoma	0.5%	0.2%
Pneumothorax	0.5%	0.4%
Seroma	0.5%	0.3%
Irritation	0.4%	0.3%
Lymphadenopathy	0.3%	0.1%
Tissue or Skin Necrosis	0.2%	0.2%

INTRODUCTION

The McGhan Medical Corporation Silicone-Filled Breast Implant Adjunct Clinical Study is a prospective, 5-year, multi-center clinical study designed to examine the safety of McGhan Silicone-Filled Breast Implants for reconstruction and revision patients. This report presents the results from the revision cohort. As this study is still ongoing, including enrollment of new patients, this report represents interim 1-year and 3-year post-implant data, with limited safety data available beyond 3 years included in Appendix A.

METHODS

A. SUBJECTS

1. Patient Enrollment

A total of 9,902 revision patients were enrolled in this study, where enrollment is defined as undergoing implant surgery. The first revision patient was enrolled on April 27, 1998 and the last revision patient implanted as of this report was enrolled on August 21, 2002. New patient enrollment is ongoing in this study.

Patients were enrolled in this study if they met the following eligibility criteria:

- Female of any age
- Primary breast revision indicated for the following:

  For affected breast:
  - Revision of implant procedure due to previous augmentation or reconstruction with silicone- or saline-filled implants where problems exist, such as implant rupture or significant capsular contracture (Baker Grade III or IV) requiring revision

  For unaffected breast:
  - Contralateral mammaplasty in unaffected breast as a result of the affected breast requiring surgery (for one of the aforementioned circumstances), when medically indicated to provide symmetry

- Adequate tissue available to cover implants
- Saline-filled implants are not an appropriate choice
- Willingness to follow all study requirements, such as agreeing to all required follow-up visits, and acceptance of the risks involved as indicated by signing of the study Patient Informed Consent document

Patients were not enrolled in the study if they had any of the following characteristics:

- Advanced fibrocystic disease considered to be premalignant without accompanying subcutaneous mastectomy
- Existing carcinoma of the breast, without mastectomy
- Abscess or infection in the body at the time of enrollment
- Pregnant or nursing
- Have any disease, including uncontrolled diabetes, which is clinically known to impact wound healing ability
- Show tissue characteristics that are clinically incompatible with mammaplasty, such as tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration
- Have, or under treatment for, any condition which, in the opinion of the surgeon, may constitute an unwarranted surgical risk
- Show psychological characteristics which, in the opinion of the surgeon, may be incompatible with the surgical procedure and the prosthesis, such as inappropriate attitude or motivation
- Wish to have augmentation mammaplasty, but do not have at least one of the diagnoses identified in Patient Inclusion Criteria
- Are not willing to undergo further surgery for revision, if medically required
- Diagnosis of lupus or scleroderma
- Replacement of saline-filled implants solely for a less than desirable cosmetic outcome, such as wrinkling

As discussed in the next section, data from 21 enrolled patients were excluded from analyses due to ineligibility. Thus, this report presents data obtained from 9,881 revision patients.

2. Excluded Patients

Twenty-one (21) patients were enrolled into the study (i.e., underwent implant surgery), but were subsequently found to be ineligible for study participation. These patients have been reported to FDA as protocol deviations in previous annual reports (April 27, 1999, April 27, 2000, April 27, 2001, April 27, 2002) or are included in an attachment to this module of the PMA submission. Thus, these patients' data were excluded from all analyses.

3. Investigators

A total of 1,272 Principal Investigators (PIs) at 2,355 sites (defined as a unique PI-IRB combination) are participating in the Adjunct Clinical Study for reconstruction or revision enrollment/follow-up. A site listing (i.e., Investigational Sites by Principal Investigator and Institutional Review Board [IRB]) is provided as an attachment to this module of the PMA submission.

B. PROCEDURE FOR DATA COLLECTION

1. Safety Data Collection

Per the study protocol, patients are required to come in for follow-up visits at 1, 3, and 5 years post-implant. Additionally, post-implant observations/complications are recorded for patients who come in for visits between scheduled visit intervals. Assessment of safety is based on the occurrence of the following:

a. Unanticipated Adverse Device Effects

An unanticipated adverse device effect is defined on the Unanticipated Adverse Event Form as:

> *any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with the McGhan Breast Implant or use of the McGhan Breast Implant, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence.*

Unanticipated adverse events are captured on an Unanticipated Adverse Event Form. All UAE Forms are reviewed by the Medical Monitor to ascertain if the reported event represents a true UAE or a known medical complication that was incorrectly reported on the UAE Form.

b. Medical Complications

All medical complications are recorded on the Follow-Up Form.

c. Reoperations

All reoperations are captured on a Secondary Procedures Form.

d. Implant Replacement/Removal

All implant replacements/removals are captured on a Secondary Procedures Form.

2. Effectiveness Data Collection

At each scheduled follow-up visit, both the physician and patient are asked to indicate their satisfaction with the implant surgery on a scale from "definitely dissatisfied" to "definitely satisfied". This data is collected on the Follow-Up Form.

C. GENERAL ANALYSIS APPROACH

1. Analysis of Data Through Three Years

The extract of the database housing the data that was used for the current report was taken on August 30, 2002.

Because this study is continuing to enroll new patients, not all patients have reached a scheduled follow-up visit time point. As of the date of final database extract, 74% of the revision patients have traversed their 1-year follow-up visit window and 24%

have traversed their 3-year follow-up visit window. No revision patients have yet traversed their 5-year follow-up visit window. As a representation of safety beyond 3 years, all post 3-year occurrences of the medical complications listed in Methods Section D.3.b are summarized in Appendix A of this report.

The results of this study are reported by specific post-implant visit intervals (i.e., 1 year, 3 years) as well as cumulatively through 3 years. Depending on the data point reported and the type of follow-up information collected, the visit intervals are defined in one of two corresponding ways.

The first approach to data analysis is based on specific follow-up time points defined in terms of number of days post-implant. Complication and reoperation information is collected by specific reported event follow-up visit dates. Thus, these outcome variables are analyzed and reported based on the specific follow-up time points in the study and are defined in exact number of days post-implant:

- 1 Year: 365 days
- 3 Years: 1095 days

The method of analysis of the complication and reoperation data is survival analysis, using the Kaplan-Meier product limit method, of the time to first occurrence of the particular event under consideration, with time assessed in days post-implant. The "Number Affected" is the number of patients/implants with at least one occurrence of the event on or before the follow-up time point being reported. The "Number Remaining" is the number of patients/implants without the reported event and who were not lost to follow-up prior to the reported follow-up time point. For each reported follow-up time point, the failure rate is provided along with the associated 95% confidence interval.

The second approach to data analysis is based on visit windows. These windows are defined in terms of intervals around each follow-up time frame. Patient compliance and satisfaction are analyzed and reported based on follow-up visit intervals defined as:

- 1 Year: 6 months, 1 day through 18 months, 0 days post-implant
- 3 Years: 30 months, 1 day through 42 months, 0 days post-implant

Discontinuation data reported "through 3 years" is inclusive of all results obtained through 42 months post-implant.

2. **Analysis of Primary Enrolled Study Implants**

This report documents the results obtained for primary enrolled study implants (i.e., original devices implanted). If a primary study implant was removed and replaced with another study device ("secondary" implant), data continues to be gathered on the secondary study implant, adhering to the patient's same ongoing study schedule as for the primary study implant. However, data collected on these secondary implants was

not included in the primary analysis. Appendix B contains a summary of the medical complications listed in Methods Section D.3.b that occurred following explant and replacement in the revision cohort.

If a patient enrolled into the study on one side only (i.e., unilaterally) and later received a study device on the contralateral side, then all by-patient analyses were performed based on the surgery date for the patient's first implant. All by-implant analyses were based on the separate implant surgery dates for each device.

Analyses were conducted using the number of patients and/or the number of implants as the unit of analysis, as appropriate. For example, all demographic data are reported by patient only, whereas data on the type of device styles are reported by implant only. Complication rates are reported both by patient and by implant (except for asymmetry, which is reported by patient only).

3. Open-Ended Response Coding

To effectively capture the relevant clinical information recorded in the open-ended "Other" complication field on the Follow-Up Form, specific categories were developed to report these responses. All open-ended responses reviewed were assigned to a category and given a corresponding numeric code that was entered into the clinical database.

A comprehensive approach was used for this coding process. When the grammatical structure of the response was confusing or incomplete, the entire clinical study form and/or patient case history was reviewed and assessed in order to adequately determine which category and code to apply. In some cases the study investigator's office was contacted to clarify the response. Specific coding rules were documented and applied to the overall coding process.

D. METHODS FOR DATA ANALYSIS

1. Patient Enrollment and Surgical Treatment

a. Demographic Variables

For each patient, the following demographic characteristics are reported:

- Age
- Marital Status
- Occupation
- Education

For marital status and occupation, the sum total of responses may be greater than the total number of enrolled patients due to the fact that all responses are reported, including multiple responses to the item for the same patient. For patients where more than one educational level was provided, the highest indicated level is reported.

b. Product Styles

A frequency distribution of device styles utilized in this study is reported by implant.

c. Surgical Complications

The number of patients who had an intraoperative complication is reported.

2. Patient Compliance and Discontinuation

Patient compliance at each follow-up visit interval is presented using the visit intervals described previously. "Theoretically Due" refers to patients who were at least 2 months past their due date for a follow-up visit (i.e., patients who should be examined according to their follow-up visit schedule).

Patients became ineligible to be followed up if they:

- died
- had all study devices removed without replacement
- had all study devices removed and replaced with non-McGhan devices
- had all study devices removed and replaced with McGhan non-study devices

The number of "Expected" patients is derived from the difference between those who were theoretically due and those who died or were discontinued due to explantation of all study devices. "Actual Evaluated" during each visit interval is defined as the number of patients who were seen for a follow-up visit at least once during the interval. "% Follow-Up" is calculated as the number of patients who were evaluated divided by the total number of expected patients for that study interval.

If the patient completes a follow-up visit and also has a discontinuation date within the same visit interval, then the patient is considered compliant for that interval and is considered discontinued in the compliance calculation for the next visit interval. In contrast, if the patient dies prior to completion of a follow-up visit, then the patient is considered discontinued in the compliance calculation for that visit interval in which her death occurred.

The following measures were taken to minimize the number of patients who were lost to follow-up:

- An active compliance follow-up program was implemented to further remind sites of which patients were due to be seen for required follow-up visits through the use of quarterly mailings to each investigator that provided their site's current percentage of patients seen for the required 1-year and 3-year follow-up visit, plus a report of patients due for a visit in the subsequent quarter
- Patients who relocated were transferred to a new Investigator in their area for follow-up; new Investigators were recruited and enrolled in the study in order to follow patients who moved to areas without an existing Investigator

- A professional search company was used to locate patients when the site was unable to reach patients at previously known addresses due to relocation

The number of patients discontinued through the end of the 3-year visit interval is reported according to one of four primary reasons for discontinuation (see Appendix C for copies of the discontinuation forms):

- Patient no longer has any McGhan silicone-filled study implants
- Patient death
- Patient choice
- Other

Appendix D contains copies of patient Discontinuation Forms for all patients discontinued after the 3-year visit interval.

3. **Safety Assessment**

a. Unanticipated Adverse Device Effects

Unanticipated Adverse Events (UAEs) were collected on the Unanticipated Adverse Event Form. The number of UAEs is reported.

b. Medical Complications

Complications were identified from the check-box questions on the Follow-Up Form. Open-ended responses capturing other complications that were not provided as check boxes on the form were coded as described previously. Complications collected were the following:

- asymmetry
- breast pain
- bruising
- capsular contracture
- capsule calcification
- delayed wound healing
- hematoma
- hypertrophic scarring
- implant extrusion
- implant malposition
- implant palpability
- implant rupture
- implant visibility
- infection
- irritation
- loss of nipple sensation
- lymphadenopathy

- nipple hypersensitivity
- nipple paresthesia
- pneumothorax
- redness
- seroma
- skin hypersensitivity
- skin paresthesia
- skin rash
- swelling
- tissue or skin necrosis
- wrinkling
- other complications (e.g., breast ptosis)

For the implant extrusion, implant rupture, and pneumothorax complications, all reported occurrences are included in the analysis regardless of the severity rating provided by the physician (i.e., very mild, mild, moderate, severe, or very severe). As determined in consultation with Inamed's Medical Advisor, Dr. Scott Spear, for all other complications, only reported occurrences that were in the moderate, severe, or very severe range are included in the analysis (for capsular contracture, Baker Grades III and IV were included in the analysis). Very mild and mild indications of these events (for capsular contracture, Baker Grades I and II) are not considered clinical problems; rather, these occurrences are within the range of what is considered normal for women with implant surgery. This method for reporting complications is identical to the approach used in the McGhan Medical PMA for saline-filled breast implants (PMA #P990074, approved May 10, 2000).

Cumulative risk (Kaplan-Meier) was used to describe these complications. The method of risk analysis used for this report is not subject to the problem of competing risks (FDA/McGhan Teleconference March 17, 2000) because once a patient experiences her first complication (e.g., breast pain at 15 days post-implant) she is not removed from the pool of patients who may experience (and be reported as having) another complication (e.g., capsular contracture at 45 days post-implant).

c. Reoperations

A "reoperation" is defined as a visit during which at least one secondary procedure was performed involving one or more primary study devices. Analyses describing reoperations are:

- Cumulative risk (Kaplan-Meier)
- Number of reoperations per patient
- Intraoperative complications during reoperation

If the only procedure performed during a reoperation was a nipple reconstruction/nipple tattoo, then the reoperation is not included in the analysis because these reoperations are considered planned. Nipple tattoo procedures were

identified by the check-box on the Secondary Procedures Form. Additionally, an effort was made to exclude reoperations that involved a nipple reconstruction procedure only (as identified by the terms "Nipple Reconstruction" or "Nipple Recon" in the open-ended 'Specify Other' procedure field on the Secondary Procedures Form).

d. Implant Replacement/Removal

Kaplan-Meier analysis is conducted on the time to first occurrence of implant replacement/removal both by patient and by implant.

4. Effectiveness Assessment

Frequency distributions of the degree of physician and patient satisfaction regarding the breast implantation are presented for each study visit interval. If more than one assessment is reported by the physician or patient during a visit interval, the worst-case (more dissatisfied) assessment indicated is reported. The total number of patients included in the satisfaction analysis for any visit interval may be different from the total number of patients seen during that interval (as indicated in the compliance table) due to the inclusion of patients who were seen for a follow-up visit but who have not yet traversed their target window, or due to the exclusion of patients for whom no assessment of their implants was made during the follow-up visit.

RESULTS

A. PATIENT ENROLLMENT AND SURGICAL TREATMENT

1. Demographic Characteristics

Tables 1 – 3

Patients' pre-implant demographic characteristics are presented in Tables 1-3.

Table 1 reports patient age and marital status. The median patient age was 44 years. A total of 58.8% of the patients were married, 19.7% were divorced, and 11.2% were single.

As reported in Table 2, a total of 42.0% of the patients were employed in professional jobs and 16.9% were housewives.

Education data are presented in Table 3. The majority (73.8%) of patients had at least some college education.

2. Product Styles

Table 4

Table 4 presents a distribution of the device styles used for the revision patients in this study. A total of 19,099 primary study devices were implanted in the 9,881 patients. Textured device styles were more commonly used (52.8%) than were

smooth styles (45.9%), and round styles were more commonly used (87.3%) than were shaped styles (11.4%). A small number of product styles are reported as unknown; these data issues are actively being followed up on with the sites.

3. Surgical Complications

Table 5

A total of 54 (0.5%) revision patients had an intraoperative complication during their primary implant surgery (Table 5).

B. PATIENT COMPLIANCE AND DISCONTINUATION

Tables 6 – 7

Of the 9,881 revision patients, 7,322 (74.1%) have traversed their 1-year follow-up visit window and 2,365 (23.9%) have traversed their 3-year follow-up visit window. Accounting for those patients who were discontinued due to death or explant of all study devices, compliance was 43.9% at the 1-year follow-up visit and 19.9% at the 3-year follow-up visit (Table 6).

Based on data obtained through 3 years, 326 of the 9,881 patients (3.3%) were discontinued from the study (Table 7). Of these, 126 patients were discontinued due to removal of all study devices, 112 patients chose to discontinue, 14 patients died, and 74 patients discontinued for other reasons. The causes of the patient deaths were cancer, murder, 9/11/01 terrorist attack, suicide, old age, and non-implant related medical conditions (e.g., stroke). "Other" reasons for discontinuation included the patient moving out of the country or not wanting to transfer to another doctor when her physician discontinued from the study.

C. SAFETY ASSESSMENT

1. Unanticipated Adverse Events

There were no Unanticipated Adverse Events (UAEs) associated with the silicone-filled breast implants in this study. Nineteen (19) Unanticipated Adverse Event Forms have been received for the revision patients. Each of the 19 reported events was reviewed by the Medical Monitor who determined that none of the observations met the definition of a UAE; rather, all reports were known medical complications (e.g., capsular contracture, infection, seroma).

2. Medical Complications

Tables 8 – 36

Tables 8-36 present the Kaplan-Meier risk analysis results for each of the medical complications assessed in this study.

The following table summarizes the 3-year risk rates and associated 95% confidence intervals for each complication, both by patient and by implant. Complications are sorted from the highest to the lowest 3-year risk rates by patient. The risks reported in this table are not additive because a patient may experience more than one complication and would be included in the risk for each complication.

Complication	3-Year Risk By Patient % (95% CI)	3-Year Risk By Implant % (95% CI)
Capsular Contracture	20.0% (17.6%, 22.3%)	15.2% (13.6%, 16.8%)
Implant Palpability	12.1% (10.0%, 14.2%)	9.3% (7.9%, 10.6%)
Wrinkling	10.6% (8.7%, 12.5%)	8.3% (7.1%, 9.6%)
Asymmetry	9.8% (7.9%, 11.6%)	N/A
Breast Pain	7.8% (6.1%, 9.4%)	5.6% (4.5%, 6.6%)
Implant Malposition	7.3% (5.6%, 8.9%)	4.8% (3.8%, 5.8%)
Implant Visibility	6.9% (5.2%, 8.6%)	5.2% (4.2%, 6.3%)
Loss of Nipple Sensation	3.7% (2.5%, 4.8%)	3.1% (2.4%, 3.9%)
Capsule Calcification	3.4% (2.3%, 4.5%)	2.4% (1.7%, 3.1%)
Implant Rupture	2.7% (1.4%, 3.9%)	1.8% (1.0%, 2.5%)
Hypertrophic Scarring	2.0% (1.3%, 2.7%)	1.5% (1.1%, 2.0%)
Nipple Hypersensitivity	1.9% (1.1%, 2.7%)	1.5% (1.0%, 2.0%)
Swelling	1.9% (1.4%, 2.5%)	1.4% (1.1%, 1.7%)
Skin Paresthesia	1.4% (0.8%, 2.1%)	0.8% (0.5%, 1.2%)
Nipple Paresthesia	1.1% (0.4%, 1.9%)	1.0% (0.5%, 1.5%)
Redness	1.0% (0.6%, 1.5%)	0.6% (0.4%, 0.9%)
Other Complications	1.0% (0.5%, 1.5%)	0.6% (0.4%, 0.9%)
Bruising	0.7% (0.4%, 1.1%)	0.5% (0.3%, 0.7%)
Infection	0.7% (0.3%, 1.2%)	0.4% (0.2%, 0.7%)
Skin Hypersensitivity	0.7% (0.2%, 1.3%)	0.6% (0.2%, 1.0%)
Delayed Wound Healing	0.6% (0.2%, 1.1%)	0.4% (0.1%, 0.6%)
Implant Extrusion	0.6% (0.3%, 1.0%)	0.6% (0.3%, 0.8%)
Skin Rash	0.6% (0.0%, 1.3%)	0.4% (0.1%, 0.7%)
Hematoma	0.5% (0.2%, 0.8%)	0.2% (0.1%, 0.4%)
Pneumothorax	0.5% (0.2%, 0.8%)	0.4% (0.2%, 0.7%)
Seroma	0.5% (0.1%, 0.9%)	0.3% (0.1%, 0.5%)
Irritation	0.4% (0.1%, 0.8%)	0.3% (0.1%, 0.5%)
Lymphadenopathy	0.3% (0.0%, 0.6%)	0.1% (0.0%, 0.3%)
Tissue or Skin Necrosis	0.2% (0.0%, 0.6%)	0.2% (0.0%, 0.5%)

The highest 3-year by-patient risk rates were observed for capsular contracture (20.0%), implant palpability (12.1%), and wrinkling (10.6%). All other complications occurred at a by-patient risk of less than 10.0%. The category "Other Complications" consists of complications that were not collected via the check boxes provided on the Follow-Up Form, such as ptosis, inadequate nipple projection, breast lump, and implant size dissatisfaction.

3. Reoperations

Tables 37 – 39

Tables 37-39 present results pertaining to reoperations performed through 3 years. The 3-year risk of reoperation was 34.5% by patient and 28.1% by implant (Table 37). A total of 982 reoperations were performed on 892 patients (9.0% of 9,881 enrolled patients) through 3 years post-implant. Most of the patients who had a reoperation (91.4%) had one reoperation (Table 38). Intraoperative complications were reported during 27 of the 982 reoperations (2.7%), (Table 39).

4. Implant Replacement/Removal

Table 40

Table 40 describes the occurrence of implant replacement/removal. The 3-year risk of implant replacement/removal (i.e., device explant with or without replacement) was 24.1% by patient and 19.5% by implant.

D. EFFECTIVENESS ASSESSMENT

Tables 41 – 42

Tables 41 and 42 report physician and patient satisfaction with the implant surgery based on primary study devices. More than 90% of physicians indicated being satisfied with the results of breast implant surgery at both the 1-year and 3-year visit intervals. Similarly, most patients indicated being satisfied with the results of their breast implant surgery at both the 1-year (90.1% of patients) and 3-year (88.2% of patients) visit intervals. On a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians and patients ranged between 4.2 and 4.4 during each follow-up interval.

DISCUSSION

Overall, the results of this study revealed that McGhan Silicone-Filled Breast Implants are safe devices for use in revision of existing breast implants. This conclusion is based on data from a total of 9,881 revision patients who received these devices and were followed for up to 3 years post-implant. Follow-up data is available for 3,180 patients at 1 year post-implant and 460 patients at 3 years post-implant, providing findings related to safety outcomes for a large number of patients.

In terms of the safety of McGhan Silicone-Filled Breast Implants, results revealed clinically acceptable rates for medical complications and reoperations at 3 years post-implant. The highest 3-year by-patient risk rates for medical complications were capsular contracture (20.0%), implant palpability (12.1%), and wrinkling (10.6%). The lowest 3-year by-patient risk rates, all of which were under 1%, were for bruising, infection, skin hypersensitivity, delayed wound healing, implant extrusion, skin rash, hematoma, pneumothorax, seroma, irritation, lymphadenopathy, and tissue or skin necrosis. The 3-

year risk of reoperation was 34.5% by patient, and the 3-year risk of implant replacement/removal was 24.1% by patient.

In terms of effectiveness, patients were highly satisfied with their breast implants. Approximately 90% of both physicians and patients reported being satisfied with the outcome of the breast implant surgery at each of the follow-up visit intervals.

In sum, the results of this study revealed that the risk of complications associated with breast implant surgery for revision of existing breast implants, including reoperations, is relatively low and patient satisfaction is very high. These results are consistent with previous findings that, despite the risks associated with breast implant surgery, women perceive significant positive benefit to the procedure (Handel et al., 1993; Young et al., 1994; McGhan Medical RTV Saline-Filled Mammary Implant PMA #P990074, Original PMA Volume 6).

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ADJUNCT REVISION TABLES

Table 1: Patient Age and Marital Status

Characteristic	Patients (N = 9881)	
	n	%
18-19	9	0.1%
20-29	572	5.8%
30-39	2215	22.4%
40-50	3479	35.2%
50-60	2382	24.1%
60-70	572	5.8%
70 & over	129	1.3%
Not Provided	523	5.3%
	9881	100.0%
Median = 44 years Range = 18 to 88 years		
Single	1111	11.2%
Married	5806	58.8%
Widowed	261	2.6%
Separated	240	2.4%
Divorced	1944	19.7%
Not Provided	541	5.5%
	9903	100.2%

Table 2: Patient Occupation

Occupation	Patients (N = 9881)	
	n	%
Clerical	871	8.8%
Professional	4146	42.0%
Trade	623	6.3%
Housewife	1672	16.9%
Not Employed	516	5.2%
Other	1521	15.4%
Not Provided	667	6.8%
	10016	101.4%

Table 3: Patient Education

Education	Patients (N = 9881)	
	n	%
Less Than High School	155	1.6%
High School Graduate	1761	17.8%
Some College	3390	34.3%
College Graduate	2806	28.4%
Post College	1093	11.1%
Not Provided	676	6.8%
	9881	100.0%

Table 4: Product Styles

Product Style	Implants (N = 19099) n	%
Smooth		
Style 10 (round)	27	0.1%
Style 20 (round)	34	0.2%
Style 40 (round)	5969	31.3%
Style 45 (round)	2728	14.3%
	8758	45.9%
Textured		
Style 110 (round)	5708	29.9%
Style 120 (round)	2203	11.5%
Style 153 (shaped)	2179	11.4%
	10090	52.8%
Unknown	251	1.3%

Table 5: Intraoperative Complications

Intraoperative Complications	Patients (N = 9881)	
	n	%
Yes	54	0.5%
No	9402	95.2%
Missing	425	4.3%
	9881	100.0%

Table 6: Patient Compliance Through 3 Years

	1 Year	3 Years
Theoretically Due	7322	2365
Deaths*	10	5
Explant-Related Discontinuations*	68	50
Without Replacement	13	8
Replacement with Non-Study Device	15	12
Unknown Replacement Status	40	30
Expected	7244	2310
Actual Number Evaluated	3180	460
(Additional Number Evaluated**)	84	53
Lost-to-Follow-Up	4064	1850
% Follow-Up	43.9%	19.9%

* Deaths and Explant-Related Discontinuations are reported cumulatively.

** These patients have been seen in their 1-year or 3-year follow-up window but have not yet traversed their target window (12-14 months or 36-38 months post-implantation); therefore, they are not counted in the "Theoretically Due" row of this table or included in the calculation of "% Follow-Up".

Table 7: Patient Discontinuation Through 3 Years

Discontinuation	Patients (N = 9881)	
	n	%
Not Discontinued	9555	96.7%
Discontinued		
Death	14	0.1%
Explanted of All Study Devices	126	1.3%
Patient Choice	112	1.1%
Other	74	0.7%
	9881	100.0%

Table 7 (cont.): Patient Discontinuation Through 3 Years

Patient Death Discontinuation Specified (N = 14)

Pt Seq#	Patient Death Discontinuation
001	CANCER TO BRAIN
002	COMPLETE RENAL FAILURE
003	CANCER-UNKNOWN PRIMARY
004	MURDERED
005	OLD AGE
006	SUICIDE
007	BREAST CANCER
008	LUNG CA
009	?HEART FAILURE
010	KILLED ON 9/11 TERRORIST ATTACK.
011	SUICIDE
012	SUICIDE/INFORMATION GATHERED FROM PERSONAL CONTACTS/NO OFFICE NOTICE
013	BREAST CA
014	STROKE

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Table 8: Risk of First Occurrence of Asymmetry

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	73	2777	2.1% (1.6%, 2.6%)		N/A	
3 Years	163	346	9.8% (7.9%,11.6%)		N/A	

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Table 9: Risk of First Occurrence of Breast Pain

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	92	2774	2.5% (2.0%, 3.0%)	127	5338	1.8% (1.5%, 2.1%)
3 Years	150	346	7.8% (6.1%, 9.4%)	203	660	5.6% (4.5%, 6.6%)

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Table 10: Risk of First Occurrence of Bruising

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	20	2788	0.5% (0.3%, 0.8%)	29	5353	0.4% (0.3%, 0.5%)
3 Years	23	349	0.7% (0.4%, 1.1%)	32	665	0.5% (0.3%, 0.7%)

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Table 11: Risk of First Occurrence of Capsular Contracture

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	164	2765	4.7% (4.0%, 5.4%)	223	5335	3.3% (2.9%, 3.8%)
3 Years	365	332	20.0% (17.6%,22.3%)	505	642	15.2% (13.6%,16.8%)

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Table 12: Risk of First Occurrence of Capsule Calcification

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	20	2797	0.6% (0.3%, 0.9%)	29	5366	0.5% (0.3%, 0.6%)
3 Years	53	351	3.4% (2.3%, 4.5%)	76	668	2.4% (1.7%, 3.1%)

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Table 13: Risk of First Occurrence of Delayed Wound Healing

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	10	2793	0.3% (0.1%, 0.4%)	12	5363	0.2% (0.1%, 0.3%)
3 Years	15	351	0.6% (0.2%, 1.1%)	17	668	0.4% (0.1%, 0.6%)

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Table 14: Risk of First Occurrence of Hematoma

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	9	2793	0.2% (0.1%, 0.4%)	9	5363	0.1% (0.0%, 0.2%)
3 Years	13	351	0.5% (0.2%, 0.8%)	13	668	0.2% (0.1%, 0.4%)

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Table 15: Risk of First Occurrence of Hypertrophic Scarring

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	10	2795	0.3% (0.1%, 0.5%)	16	5363	0.3% (0.1%, 0.4%)
3 Years	40	346	2.0% (1.3%, 2.7%)	61	660	1.5% (1.1%, 2.0%)

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Table 16: Risk of First Occurrence of Implant Extrusion

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	9	2795	0.2% (0.1%, 0.4%)	12	5365	0.2% (0.1%, 0.3%)
3 Years	16	346	0.6% (0.3%, 1.0%)	26	658	0.6% (0.3%, 0.8%)

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Table 17: Risk of First Occurrence of Implant Malposition

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	61	2785	1.8% (1.3%, 2.2%)	75	5358	1.1% (0.9%, 1.4%)
3 Years	126	345	7.3% (5.6%, 8.9%)	158	662	4.8% (3.8%, 5.8%)

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Table 18: Risk of First Occurrence of Implant Palpability

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	63	2785	1.9% (1.4%, 2.4%)	80	5357	1.3% (1.0%, 1.5%)
3 Years	185	339	12.1% (10.0%,14.2%)	264	652	9.3% (7.9%,10.6%)

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Table 19: Risk of First Occurrence of Implant Rupture

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	12	2794	0.3% (0.1%, 0.5%)	14	5365	0.2% (0.1%, 0.3%)
3 Years	30	346	2.7% (1.4%, 3.9%)	39	659	1.8% (1.0%, 2.5%)

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Table 20: Risk of First Occurrence of Implant Visibility

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	40	2788	1.2% (0.8%, 1.6%)	60	5357	0.9% (0.7%, 1.2%)
3 Years	99	343	6.9% (5.2%, 8.6%)	148	658	5.2% (4.2%, 6.3%)

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Table 21: Risk of First Occurrence of Infection

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	16	2793	0.4% (0.2%, 0.6%)	20	5363	0.3% (0.2%, 0.4%)
3 Years	19	351	0.7% (0.3%, 1.2%)	23	668	0.4% (0.2%, 0.7%)

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Table 22: Risk of First Occurrence of Irritation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	5	2795	0.1% (0.0%, 0.2%)	5	5365	0.1% (0.0%, 0.1%)
3 Years	9	350	0.4% (0.1%, 0.8%)	10	667	0.3% (0.1%, 0.5%)

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Table 23: Risk of First Occurrence of Loss of Nipple Sensation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	24	2791	0.7% (0.4%, 1.0%)	39	5357	0.6% (0.4%, 0.8%)
3 Years	62	344	3.7% (2.5%, 4.8%)	101	657	3.1% (2.4%, 3.9%)

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Table 24: Risk of First Occurrence of Lymphadenopathy

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	3	2796	0.1% (0.0%, 0.2%)	3	5365	0.0% (0.0%, 0.1%)
3 Years	5	350	0.3% (0.0%, 0.6%)	5	667	0.1% (0.0%, 0.3%)

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Table 25: Risk of First Occurrence of Nipple Hypersensitivity

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	13	2794	0.4% (0.2%, 0.6%)	18	5363	0.3% (0.1%, 0.4%)
3 Years	33	348	1.9% (1.1%, 2.7%)	48	664	1.5% (1.0%, 2.0%)

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Table 26: Risk of First Occurrence of Nipple Paresthesia

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	3	2796	0.1% (0.0%, 0.2%)	5	5364	0.1% (0.0%, 0.2%)
3 Years	15	351	1.1% (0.4%, 1.9%)	23	668	1.0% (0.5%, 1.5%)

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Table 27: Risk of First Occurrence of Pneumothorax

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	5	2795	0.1% (0.0%, 0.3%)	6	5365	0.1% (0.0%, 0.2%)
3 Years	11	347	0.5% (0.2%, 0.8%)	18	660	0.4% (0.2%, 0.7%)

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Table 28: Risk of First Occurrence of Redness

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	22	2789	0.6% (0.3%, 0.8%)	28	5359	0.4% (0.2%, 0.5%)
3 Years	28	350	1.0% (0.6%, 1.5%)	34	667	0.6% (0.4%, 0.9%)

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Table 29: Risk of First Occurrence of Seroma

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	12	2794	0.3% (0.1%, 0.5%)	13	5364	0.2% (0.1%, 0.3%)
3 Years	13	350	0.5% (0.1%, 0.9%)	14	667	0.3% (0.1%, 0.5%)

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Table 30: Risk of First Occurrence of Skin Hypersensitivity

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	7	2796	0.2% (0.0%, 0.3%)	10	5366	0.1% (0.1%, 0.2%)
3 Years	13	351	0.7% (0.2%, 1.3%)	18	668	0.6% (0.2%, 1.0%)

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Table 31: Risk of First Occurrence of Skin Paresthesia

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	8	2795	0.2% (0.1%, 0.4%)	9	5365	0.1% (0.1%, 0.2%)
3 Years	25	349	1.4% (0.8%, 2.1%)	30	666	0.8% (0.5%, 1.2%)

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Table 32: Risk of First Occurrence of Skin Rash

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	% (95% CI)		n	n	% (95% CI)	
1 Year	6	2795	0.2% (0.0%, 0.3%)		11	5363	0.2% (0.1%, 0.3%)	
3 Years	8	350	0.6% (0.0%, 1.3%)		13	666	0.4% (0.1%, 0.7%)	

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Table 33: Risk of First Occurrence of Swelling

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	58	2775	1.5% (1.1%, 1.9%)	86	5337	1.2% (0.9%, 1.4%)
3 Years	63	347	1.9% (1.4%, 2.5%)	92	662	1.4% (1.1%, 1.7%)

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Table 34: Risk of First Occurrence of Tissue or Skin Necrosis

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	1	2797	0.0% (0.0%, 0.1%)	2	5366	0.0% (0.0%, 0.1%)
3 Years	2	351	0.2% (0.0%, 0.6%)	4	668	0.2% (0.0%, 0.5%)

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Table 35: Risk of First Occurrence of Wrinkling

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	77	2788	2.3% (1.8%, 2.8%)	108	5355	1.7% (1.3%, 2.0%)
3 Years	185	339	10.6% (8.7%,12.5%)	273	651	8.3% (7.1%, 9.6%)

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Table 36: Risk of First Occurrence of Other Complications

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	13	2797	0.4% (0.2%, 0.6%)	18	5366	0.3% (0.1%, 0.4%)
3 Years	22	351	1.0% (0.5%, 1.5%)	28	668	0.6% (0.4%, 0.9%)

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Table 37: Risk of First Occurrence of Reoperation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	688	2737	16.6% (15.5%,17.8%)	918	5286	12.1% (11.4%,12.8%)
3 Years	892	333	34.5% (31.9%,37.0%)	1248	651	28.1% (26.3%,29.9%)

Table 38: Number of Reoperations Per Patient

	Patients (N = 9881)	
	n	%
No Reoperations	8989	91.0%
At Least One Reoperation	892	9.0%
Total	9881	100.0%
Breakdown (# of Reoperations)		
1	815	91.4%
2	66	7.4%
3	9	1.0%
4	2	0.2%
Total	892	100.0%
Total Number of Reoperations	982*	100.0%

* Total number of reoperations is calculated as:
(815*1 reoperation) + (66*2 reoperations) +
(9*3 reoperations) + (2*4 reoperations) = 982 reoperations

Table 39: Intraoperative Complications During Reoperation

Intraoperative Complications	Reoperations (N = 982)	
	n	%
Yes	27	2.7%
No	939	95.6%
Missing	16	1.6%
	982	100.0%

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Table 40: Risk of First Occurrence of Implant Replacement/Removal

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
1 Year	445	2808	11.1% (10.1%,12.0%)	570	5424	7.6% (7.0%, 8.2%)
3 Years	576	355	24.1% (21.7%,26.5%)	791	683	19.5% (17.8%,21.1%)

Attachment 12

ADJUNCT STUDY - REVISION

Table 41: Physician Assessment of Implants

Time	Patients N	Satisfaction Level* (Allowable Range 1 - 5) Definitely Dissat-isfied %	Somewhat Dissat-isfied %	Somewhat Satisfied %	Definitely Satisfied %	Descriptive Statistics Mean	SD
1 Year	3088	3.5%	5.2%	6.3%	21.9%	63.1%	4.4	1.0
3 Years	486	3.7%	5.3%	8.2%	22.6%	60.1%	4.3	1.1

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

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Table 42: Patient Assessment of Implants

		Satisfaction Level* (Allowable Range 1 - 5)							
		Definitely Dissat-	Somewhat Dissat-	Somewhat		Definitely	Descriptive Statistics		
Time	Patients N	isfied %	isfied %	Satisfied %	Satisfied %	Satisfied %	Mean	SD	
1 Year	3150	4.5%	5.4%	7.8%	21.1%	61.2%	4.3	1.1	
3 Years	498	5.2%	6.6%	7.4%	22.7%	58.0%	4.2	1.2	

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

ADJUNCT REVISION APPENDICES

APPENDIX A

List of Complications Occurring Beyond 3 Years (1095 Days) Post-Implant

Appendix A: List of Complications Occurring Beyond 3 Years (1095 Days) Post-Implant

Complication	# of Post 3-Year Occurrences	
	Patients (n = 58)	Implants (n = 84)
Asymmetry	12	14
Breast Pain	9	10
Bruising	0	0
Capsular Contracture	26	39
Capsule Calcification	4	6
Delayed Wound Healing	0	0
Hematoma	1	1
Hypertrophic Scarring	1	1
Implant Extrusion	1	2
Implant Malposition	5	6
Implant Palpability	11	17
Implant Rupture	1	2
Implant Visibility	7	11
Infection	0	0
Irritation	1	1
Loss of Nipple Sensation	3	6
Lymphadenopathy	0	0
Nipple Hypersensitivity	3	6
Nipple Paresthesia	1	2
Pneumothorax	1	2
Redness	0	0
Seroma	0	0
Skin Hypersensitivity	1	2
Skin Paresthesia	3	5
Skin Rash	0	0
Swelling	0	0
Tissue or Skin Necrosis	0	0
Wrinkling	10	15
Other Complications	1	2

APPENDIX B

Summary of Complications Following Primary Implant Removal With Replacement

Appendix B: Summary of Complications Following Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (n = 28)	Implants (n = 36)
Asymmetry	4	5
Breast Pain	5	5
Bruising	1	1
Capsular Contracture	7	9
Capsule Calcification	1	1
Delayed Wound Healing	2	2
Hematoma	1	1
Hypertrophic Scarring	0	0
Implant Extrusion	1	1
Implant Malposition	5	7
Implant Palpability	8	12
Implant Rupture	0	0
Implant Visibility	10	15
Infection	3	3
Irritation	1	1
Loss of Nipple Sensation	5	7
Lymphadenopathy	0	0
Nipple Hypersensitivity	1	1
Nipple Paresthesia	2	3
Pneumothorax	0	0
Redness	2	2
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	2	3
Skin Rash	0	0
Swelling	2	2
Tissue or Skin Necrosis	2	2
Wrinkling	7	10
Other Complications	0	0